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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/441,723 11/16/99 HILLMAN

J PF-0430-1-DI

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HM22/0323

EXAMINER

WELLS, M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED:

03/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/441,723

Applicant(s)

HILLMAN ET AL.

Examiner

Matthew O. Wells

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,14-19 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1,2,14-19 and 22-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 2, and 14, drawn to the polypeptide glutathione S-transferase (GSTS), classified in class 435, subclass 193.
 - II. Claim 15, drawn to antibodies specific for GSTS, classified in class 530, subclass 388.26.
 - III. Claim 16, drawn to GSTS agonists, which cannot be classified without further identification of the agonists.
 - IV. Claim 17, drawn to GSTS antagonists, which cannot be classified without further identification of the antagonists.
 - V. Claims 18-19, drawn to therapeutic methods, which cannot be classified without further identification of the antagonists.
 - VI. Claim 22, drawn to a method of producing an antibody to GSTS, classified in class 436, subclass 547.
 - VII. Claims 23-24, drawn to a method of screening using the GSTS polypeptide, classified in class 435, subclass 7.1.
 - VIII. Claim 25, drawn to a method of purification using the GSTS polypeptide, classified in class 530, subclass 413.

If Group VII is elected, a further election of species is required as set forth below.

Art Unit: 1642

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

- a. DNA molecules, RNA molecules, nucleic acids
- b. peptides,
- c. agonists,
- d. antagonists,
- e. antibodies, immunoglobulins,
- f. pharmaceutical agents,
- g. drug compounds.

These groups are distinct as they have different structures and functions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 23 and 24 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Art Unit: 1642

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. The inventions are distinct, each from the other because of the following reasons:

a. Inventions I-IV are unrelated products. In the instant case the different products have different structures, functions, effects and/or modes of operation. An agonist stimulates or initiates an action when it binds to a receptor, whereas an antagonist inhibits or blocks the action or stimulation when it binds to a receptor. The antagonist and antibody are structurally different.

b. Inventions V-VIII are unrelated methods. In the instant case the different inventions relate to methods but each method differs in method steps, modes of operation, reagents needed and serve different endpoints and effects.

c. Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of group I, while it can be used to produce an antibody, as claimed in group VI, can also be used in affinity purification or diagnostic testing.

d. Inventions I and VII-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

Art Unit: 1642

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of group I, while it can be used to screen and purify molecules or compounds which bind to it, as claimed in groups VII and VIII, respectively, the polypeptide can also be used in antibody production.

e. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antagonists can be used to treat or prevent an immune response or cancer. However, the methods of group V could also use an antibody, which is structurally different from the antagonist, to the polypeptide to treat or prevent the immune response or cancer.

4. Because these inventions are distinct for the reasons given above and require different search strategies, restriction for examination purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various

Art Unit: 1642

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew O. Wells whose telephone number is 703-308-4521. The examiner can normally be reached on M-F (7:00-4:30), every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Matthew Wells
March 21, 2001

Anthony C. Caputa
ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1000

Art Unit: 1642